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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,505	04/06/2001	Eyal Raz	UCAL-203	6822
7590 12/16/2003 Carol L. Francis BOZICEVIC, FIELD & FRANCIS LLP Suite 200 200 Middlefield Road Menlo Park, CA 94025			EXAMINER NGUYEN, QUANG	
			ART UNIT 1636	PAPER NUMBER
DATE MAILED: 12/16/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/828,505

Applicant(s)

RAZ ET AL.

Examiner

Quang Nguyen, Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7, 10, 14, 20, 21, 23-25 and 27-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5, 7, 10, 14, 20, 21, 23 and 27-36 is/are rejected.
- 7) ☒ Claim(s) 24, 25 and 37-39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment filed on 9/11/03 has been entered.

Claims 2-5, 7, 10, 14, 20-21, 23-25 and 27-39 are pending in the present application, and they are examined on the merits herein.

Claim Objections

Claims 2, 23, 27, 34, 36 and 37-39 are objected to because the term "a signal sequence" refers to a short peptide sequence that directs newly synthesized secretory or membrane proteins to and through membranes of the endoplasmic reticulum of a mammalian cell (see specification, page 23, last paragraph), then how is a nucleic acid encoding a plant allergen modified by including said signal sequence? Or how a signal sequence (a peptide sequence) is operably linked to an allergen-encoding sequence (a nucleic acid sequence)? It appears that Applicants refer to a nucleic acid that encodes a signal sequence, and therefore as written the claims are not grammatically correct. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Singh et al. (U.S. Patent No 5,965,455) as evidenced by Schultz et al. (Gene 54:113-123, 1987) for the same reasons already set forth in the previous Office Action (pages 7-8).

Response to Argument

Applicants' arguments related to the above rejection in the Amendment filed on 9/11/03 (pages 7-8) have been fully considered, but they are not found persuasive.

Applicants argue that there is no disclosure or suggestion anywhere in Singh of a polynucleotide comprising a nucleic acid encoding a plant allergen modified to include a signal sequence derived from a phylum or kingdom other than the phylum or kingdom from which the plant allergen is derived. Additionally, JRY88 is not a vector but a yeast strain. Applicants further argue that Singh does not disclose specifically the pYEBVC-1 vector of Schultz. Accordingly, Singh can not anticipate the instant claim.

In response, the Examiner notes that Singh teaches clearly to express and purify Lol p Ib proteins and fragments or peptides (the fragments or peptides do not contain native signal sequence) from host cells as well as from the cell culture medium (col. 12, lines 6-8). Singh further teach specifically that suitable vectors for expression in yeast cells include the vectors taught by Schultz et al. disclosed in Gene 54:113-123, 1987 (see col. 11, lines 18-21). Both the yeast expression vectors (pYEBV-1 and pYEBV-2) that are disclosed in the Schultz reference cited by Singh contain a yeast MF α 1 promoter and yeast pre-pro-leader polypeptide fused to a gene product of interest (page 115, col. 1, top of last paragraph). Accordingly, Singh teaches to express Lol p Ib

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fragments or peptides under the control of a yeast MF α 1 promoter with the yeast pre-pro-leader polypeptide fused to the Lol P Ib protein fragments or peptides in the same manner as taught by Schultz et al.

Accordingly, the teachings of Singh meet every limitation of the instant claim, and therefore Singh anticipates the instant claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al. (U.S. Patent No 5,965,455) as evidenced by Schultz et al. (Gene 54:113-

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123, 1987) and in view of Kim et al. (Gene 199: 293-301, 1997; IDS) for the same reasons already set forth in the previous Office Action (pages 8-10).

Response to Argument

Applicants' arguments related to the above rejection in the Amendment filed on 9/11/03 (pages 8-9) have been fully considered, but they are not found persuasive.

Applicants argue mainly Singh neither discloses nor suggests a polynucleotide comprising a nucleic acid encoding a plant allergen modified to include a signal sequence derived from a phylum or kingdom other than the phylum of kingdom from which the plant allergen is derived, and that Kim does not cure this deficiency.

On the contrary to Applicants' position, Singh teaches clearly to express and purify Lol p Ib proteins and fragments or peptides (the fragments or peptides do not contain native signal sequence) from host cells as well as from the cell culture medium (col. 12, lines 6-8). Singh further teach specifically that suitable vectors for expression in yeast cells include the vectors taught by Schultz et al. disclosed in Gene 54:113-123, 1987 (see col. 11, lines 18-21). Both the yeast expression vectors (pYEBV-1 and pYEBV-2) that are disclosed in the Schultz reference cited by Singh contain a yeast MF α 1 promoter and yeast pre-pro-leader polypeptide fused to a gene product of interest (page 115, col. 1, top of last paragraph). Accordingly, Singh teaches to express Lol p Ib fragments or peptides under the control of a yeast MF α 1 promoter with the yeast pre-pro-leader polypeptide fused to the Lol P Ib protein fragments or peptides in the same manner as taught by Schultz et al.

Therefore, claims 2 and 4 remain rejected for the same reasons already set forth in the previous Office Action (pages 8-10).

Claims 7 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al. (U.S. 5,776,761) in view of Singh et al. (U.S. Patent No 5,965,455) and Schultz et al. (Gene 54:113-123, 1987) for the same reasons already set forth in the previous Office Action (pages 10-12).

Response to Argument

Applicants' arguments related to the above rejection in the Amendment filed on 9/11/03 (pages 9-10) have been fully considered, but they are not found persuasive.

Applicants argue mainly that Rogers does not specifically teach the preparation of nucleic acid sequences coding for Amba1 allergic proteins or peptides, wherein such nucleic acids contain a heterologous signal sequence, and that Singh can not cure the deficiency of Rogers because Singh also does not disclose or suggest a polynucleotide comprising a nucleic acid encoding a plant allergen modified to include a signal sequence derived from a phylum or kingdom other than the phylum or kingdom from which the plant allergen is derived.

Once again, Applicants' arguments with respect to the Singh patent are found to be unpersuasive for the same reasons already set forth in the above responses to Applicants' arguments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-5, 7, 10, 14, 20, 21, 27-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new ground of rejection.**

Claims 2, 27, 34, 36 and their dependent claims are vague and indefinite in that the metes and bounds of the term “derived from” are unclear. It is unclear the nature and number of steps required to obtain a “derivative” of a plant allergen and/or signal sequence. The term implies a number of different steps that may or may not result in a change in the functional characteristics of a plant allergen and/or a signal sequence from the source that it is “derived from”. It is unclear how closely related to the starting material the “derivative” is? It would be remedial to amend the claim language to use the term “obtained from”, which implies a more direct method of acquiring the plant allergen and/or signal sequence.

Additionally, in claim 2 and its dependent claims it is unclear what is encompassed by the phrase “a plant allergen derived from a non-host species of a first phylum or first kingdom”. This is because it is unclear what is the relationship or connection between a non-host species of a first phylum or first kingdom with a plant allergen? Doesn't a plant belong to a plant phylum or plant kingdom? Clarification is requested because the metes and bounds of the claims are not clearly determined.

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Conclusions

No claims are allowed.

Claims 24-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (703) 308-1906, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Quang Nguyen, Ph.D.


DAVID GUZO
PRIMARY EXAMINER